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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/067,995      | 02/08/2002  | Vincent Fischetti    | NH-Methon Upper     | 4192             |

7590 01/07/2005

JONATHAN E. GRANT  
2107 HOUND RUN PLACE  
SILVER SPRING, MD 20906

EXAMINER

PRATS, FRANCISCO CHANDLER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 01/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/067,995

Applicant(s)

FISCHETTI ET AL.

Examiner

Francisco C. Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8, 10-24 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 10-24 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 26, 2004, has been entered.

Claims 8, 10-24 and 28 are pending and are examined on the merits.

***Terminal Disclaimer***

The terminal disclaimer filed on October 26, 2004, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Pat. No. 6,238,661 and the patent arising from application serial number 09/560,650, now U.S. Pat. No. 6,752,988, has been reviewed and is accepted. The terminal disclaimer has been recorded.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 10-24 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,985,271, claims and claims 1-14 of U.S. Patent No. 6,326,002. Although the conflicting claims are not of identical scope, they are not patentably distinct from each other because the patented claims recite methods for treating the same disease condition, streptococcal infection and/or infection by *Haemophilus influenzae*, using the same enzyme and the same carriers. With respect to claim 28, note specifically that one of ordinary skill viewing the patented claims would have recognized the

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suitability of treating more than one upper respiratory tract pathogen.

It is noted that the claims of neither of these patents recites the treatment of *Haemophilus influenzae* and *Streptococcus pneumoniae*. However, the claims of the '271 and '002 patents are generically directed to treating streptococcal upper respiratory tract infections, using an enzyme from phage-infected group C streptococcal bacteria. Thus, the claims of the '271 and '002 patents encompass the treatment of infection by *Streptococcus pneumoniae*. Moreover, the artisan of ordinary skill, recognizing from the claims of the '271 and '002 patents that lytic enzyme would be suitable for use in treating respiratory tract infections, clearly would have been motivated to have used lytic enzymes to have treated infection by pathogens other than those explicitly recited in the claims of the '271 and '002 patents. Therefore, absent a terminal disclaimer over the patented claims, a holding of obviousness-type double patenting is clearly required.

Thus, a terminal disclaimer is clearly required.

Claims 8, 10-24 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application

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No. 10/067,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite methods of administering the same enzymes to treat infections caused by the same bacterial agents in the same part of the body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

All of applicant's argument regarding the pending grounds of rejection has been fully considered but is not persuasive of error. While applicant has presented a graph depicting only nominal lysis of *Streptococcus pneumoniae* by the phage C1 lysin, the graph was not filed with any underlying explanation such that a determination of the validity and accuracy of the data can be assessed. Moreover, on the current record, the graph appears to suggest that there is at least a little bit of lysis occurring when the C1 lysin recited in the claims of the '271 patent, the '002 patent and the '979 application (now allowed) is applied to *Streptococcus pneumoniae*. While this observation may be clarified by explanation, the Rule 132 declaration mentioned in applicant's response has not yet been submitted. Thus, until the record is clarified in this regard, the

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obviousness-type double patenting rejections over the '271 patent, the '002 patent and the '979 application (now allowed) must be maintained.

No claims are allowed.

This is a continued examination of applicant's earlier Application No. 10/067,995. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however,

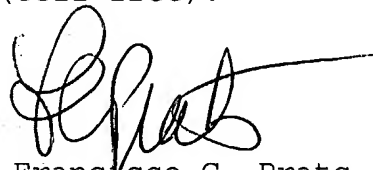
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event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C. Prats  
Primary Examiner  
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FCP